Kraft Foods

Jean E. Spence
Senior Vice President
Worldwide Quality, Scientific Affairs & Compliance

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Stuart Shapiro
FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th St., N.W.
Room 10235
Washington, D.C. 20503

Re: Registration of Food Facilities
Docket No. 02N-0276; RIN 0910-AC40

Dear Mr. Shapiro:

At Kraft Foods the safety of our products is of paramount importance, since our well known, highly trusted brands are found in 99.6% of US households and sold in 150 countries around the world. Kraft is a $30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. As Kraft celebrates it's centennial year, the trust that we have built over the last 100 years is invaluable and critical to our continued success. In addition, approximately 1000 Kraft facilities will be registered under the regulations the Food and Drug Administration (FDA) is developing. Thus, our interest in this proceeding is substantial.

Kraft commends the dedicated FDA personnel who are diligently attempting to implement the Bioterrorism Act in record time. We understand the pressure under which the agency's officials have been operating and the long hours they have invested. We appreciate their service.

From our point of view, however, the stringent time constraints imposed upon this proceeding only increase the importance of incorporating into the final rule reasonable recommendations from responsible stakeholders like Kraft. We have carefully evaluated the implications of the proposed rules. In these comments, when we have objected to an approach proposed by the agency, we have offered alternative approaches that we believe to be constructive. We ask both the Office of Management and Budget (OMB) and FDA to consider our comments realizing that we share the government's goal: protecting the safety of the US food supply.

02N-0276 C43

Kraft is particularly concerned about two aspects of the rules FDA proposed. Our first concern is related to the usefulness of collecting--or rather the futility of collecting--"FDA product code" categories for each registered food "manufacturer/processor" facility. Kraft urges the government not to adopt this proposal, but instead to make the collection of "establishment type" data mandatory, rather than voluntary (see section 9 of the proposed registration form).

Our second concern is related to the mechanics of gathering the registration data. While we agree that interactive registration over the Internet is likely to be efficient both for FDA and for companies registering only a few facilities, we recommend that the agency also accept transmission of electronic data files in lieu of interactive data entry. Offering companies registering a large number of facilities the option to process registration data electronically, but without using time consuming interactive data entry, will reduce entry errors and permit both the agency and larger companies to accomplish the massive registration task as efficiently as possible.

The reasons for our recommendations are explained below in answer to the key questions that OMB will be examining as required by the Paperwork Reduction Act.

Is the information necessary and will it have practical utility?

The Bioterrorism Act gives FDA discretion to gather general food category data, but the law does not mandate collection of such information. The general food categories identified under 21 CFR 170.3 Section 170.3 are to be used, if FDA does determine that product category information for each facility is necessary. FDA has correctly acknowledged the problems associated with use of the outdated, irrelevant 170.3 categories. Instead, the agency has tentatively decided to require submission of "FDA product code" categories instead, concluding, we think incorrectly, that tracking FDA product code categories

> "...is necessary for a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency, because the categories will assist FDA in conducting investigations and surveillance operations in response to such an incident. These categories will also enable FDA to quickly alert facilities potentially affected by such an incident if FDA receives information indicating the type of food affected."

68 Fed. Reg. 5384. The agency's speculation that a potential threat to the food supply might be framed in terms of highly technical "FDA product code" category definitions is at best unrealistic.

The proposed categories bear no relationship to bioterrorism risk; so, collecting information about the categories associated with each facility would not be useful in reducing threats to the food supply. As a practical matter, the categories are hard to work with, even for the import specialists at brokerage firms who must deal with them every day. Some categories overlap each other, yet many foods fall into gaps among the categories, so deciding which category FDA would deem correct can be quite difficult. Divining the proper category also is a struggle because the categorization scheme is in many respects counter-intuitive. Therefore, manufacturers are likely to classify similar products differently or make mistakes in reporting category classification.

Examples may help to explain the difficulty we see with the use of the "FDA product code" categories.

- If Kraft had not had prior experience importing ready to eat chocolate pudding from Canada, we would not have been familiar enough with the "FDA product codes" to know that this type of pudding is classified in the category "*bakery products, dough mixes, or icings*." We probably would have placed the product in the category described on the form as "*gelatin, rennet, pudding mixes, or pie fillings*," even though the pudding is not in mix form; or perhaps we might have selected the category described as "*chocolate and cocoa products*." Both choices would have been incorrect under the agency's product code builder scheme, for which there is a tutorial on the fda.gov web site.
- There are virtually no products on the market today labeled "imitation," yet FDA proposes "*imitation dairy products*" as a product category that must be tracked to avert risk of bioterrorism. In fact, the "imitation" designation always was solely economic--to protect consumers from spending money on products that are not "true" dairy products--and unrelated to safety or even to commonality of product composition.
- The single category 170.3(n) (3) (beverages and beverage bases) is referenced after 4 different "FDA product code" categories on the proposed registration form. We fail to see the benefit of attempting to distinguish facilities that make beverage bases, from those that make soft drinks and water, cocoa drinks, or coffee and tea. Into which category should we place a mocha coffee beverage base?
- Similarly, why does a registration need to tell FDA whether candy is made with or without chocolate? Does "without chocolate" mean without chocolate liquor or without chocolate and cocoa products?
- Why should facilities making dressings and condiments be distinguished from those making gravies and sauces? The distinction between sauces

and dressings is unquestionably arbitrary and easily subject to varying interpretations.

- Likewise, is a fruit sauce a "*fruit product*" or a "*sauce*"? Banana sauce belongs in the "FDA product code" category for "*multiple food dinners, gravies, sauces, and specialties*," yet banana topping and syrup are classified in the category "*fruits and fruit products.*"

Thus, under the FDA proposal, for each product (stock keeping unit or "SKU") a company makes, the company must take the time and spend the money to determine the accurate "FDA product code", and then from that detail, determine the "FDA product code" category. Alternatively, the company could guess the correct category based upon the agency's descriptions on the form. The latter, more expedient, approach inevitably would lead to classification inconsistency, if not to a database full of useless information. Incidentally, Kraft alone makes over 18,000 SKUs. In short, the "FDA product code" categories simply are no more workable or useful in fostering the agency's mission of maintaining the safety of the food supply than would be the 170.3 categories FDA properly rejected.

Moreover, company officials are required to certify that all registration information is "true and accurate." The preamble tells us that FDA will consider false information to be "a materially false, fictitious, or fraudulent statement to the US government under 18 USC 1001, which subjects the person [submitting the information] to criminal penalties." 68 Fed. Reg. 5385. The Kraft position is that no one should even potentially be subject to criminal penalties for failing to discern the idiosyncrasies of the "FDA product code" system.

In the FDA training video on the proposed registration regulations, agency personnel talk about the importance of using product category information for "targeted communication," a concept that appears to be based on the faulty premise that only facilities making one or a few of the identified FDA categories would need to know about a potential threat. 68 Fed. Reg. 5384-5385. In fact, all food manufacturers need to know about potential security issues, just as all learn from recall information. Information about potential security issues helps companies understand the mechanisms underlying various threats and prepare accordingly.

Furthermore, it is important to recognize that one food manufacturer's product is another's ingredient. Most of the proposed FDA categories are for foods that are virtually ubiquitous throughout the food supply, like cheese, dried milk products, flours, and vegetable oils. "Targeted communication" would address only primary ingredient manufacturers, not processors throughout the system that use those ingredients in other food products. Improperly targeted communication based upon the "FDA product code" categories would hinder, rather than foster, effective response to a potential threat as well as the associated FDA investigations and surveillance operations.

The agency's "targeted communication" concept also presumes that a serious threat would not need to be public. If that presumption were correct, public media would not be needed routinely in Class I recall situations.

The proposed rules appropriately require submission of the emergency contact information FDA unquestionably needs for "a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency." Kraft recommends that the agency expand that section of the form, so that food companies can provide a back up to the identified primary emergency contact person. At our company, for example, the main security telephone number always can be used to reach the people on the Special Situation Management Team. We would like to provide that phone number in addition to all the contact information for our primary emergency contact, just in case unforeseen circumstances make back up necessary.

FDA will not need to rely upon the emergency contact information alone, however. The emergency contact information will be amplified by "establishment type" information gathered as part of the registration process and also by the ingredient and product tracking records companies will be required to maintain under the Bioterrorism Act.

In summary, collection of "FDA product code" category data is not required by the Bioterrorism Act, is unnecessary for the accomplishment of the agency's mission, and is not useful as a practical matter. Tracking "FDA product code" categories for each facility would increase the cost of the registration system and divert resources that should be focused elsewhere, but would not improve the agency's capacity to protect the public. With the emergency contact information requested on the registration form, FDA will have the best possible means of reaching key decision makers quickly, so proper actions can be taken immediately by people who are familiar with their company's products, systems, and distribution practices.

Is the agency's estimate of the burden of collecting the information accurate?

The agency's cost estimates are understated and based on assumptions that do not reflect typical operating practices. To research and understand the rules, any company would need far more than the one hour FDA factored into the economic impact assessment. The proposal is 40 pages of fine print in the Federal Register. The agency's video takes another hour to watch. No time was allocated for the task of evaluating the implications of the proposed rules to current business systems or for preparing comments. When the final rules are published, assuring compliance will involve reading and understanding the final Federal Register document as well as any accompanying question and answer documents or videos. The "FDA product code" is not used by industry, so companies first will need to learn the agency's system and then will need to classify products by facility. FDA proposes to require management

certification that the submission is accurate, but does not appear to have factored the time the manager needs to learn the agency's requirements into the economic analysis. No systems development costs were included. Furthermore, the actual average wage rate at Kraft for the type of personnel who would be responsible for registration activities is $75 hourly (including benefits), far more than the $33 per hour weighted average wage rate used by FDA.

In spite of what we think are numerous errors in the economic analysis, our principal objection to the proposed registration rules remains the cost of collecting the irrelevant "FDA product code" data. Of all the information FDA proposes to collect, only the product category information would change constantly, as manufacturers move product lines to achieve optimum use of their facilities. At Kraft, we average about a change per week within the US, not counting changes that occur worldwide. Thus, tracking FDA product categories would not only be difficult initially, for the reasons previously discussed, but would require monthly updates. Therefore, FDA has significantly under estimated the cost of constantly keeping the registration data up to date after the information is first gathered. The ongoing cost of maintaining the registrations would far exceed the initial registration cost. Moreover, processing constant minor registration changes related to changing food categories would not be a good use of FDA or industry resources.

How could the quality, utility, and clarity of the information be enhanced?

In addition to the information required by statute, FDA proposes to ask for information on establishment types and type of storage for warehouses. This information would not change frequently, as would product categories, and might well be useful to FDA. For example, the establishment type information would make it possible for FDA to segregate manufacturing facilities from all the other types of facilities required to register. FDA is unlikely to get full voluntary compliance with the request for establishment and storage type information, when penalties would be imposed if this optional information were inaccurate when submitted initially or became out of date. Therefore, we suggest that establishment type data and type of storage for warehouses should be made mandatory or deleted entirely.

What could be done to minimize the burden of the collection of information on those who are to respond?

FDA could reduce the burden of collecting the information, if multi-facility registrants were able to send a single transmission containing all of the requisite data, in lieu of entering the data interactively over the Internet. The interactive Internet data entry approach is probably excellent for many small manufacturers, but is too time consuming for companies, like Kraft, that must register hundreds of facilities. Assuming the 1 hour FDA data entry estimate were correct, Kraft would need 1000 hours to enter data for our facilities. Even at 40 hrs per week, the task would take 25 weeks, far more than the 8 weeks provided, if only one person could be entering data interactively for a single company at a time. Thus, we suggest that the final rule include a format for submitting electronic data files, such as XML documents, Microsoft Excel documents, or standard flat files. Additionally, we recommend that the agency make provisions for a single registrant to stop entering data and begin again another day. We also think the agency should provide for a single registrant to enter data simultaneously from more than one desktop.

Conclusion

Americans depend upon both industry and government to assure the safety of the food supply. Deploying government and industry resources as effectively and efficiently as possible is critical. Adjusting the information collection requirements and the data transmission methods proposed for FDA facility registrations as we have suggested will enable industry and FDA to comply with Congressional directives without wasting or misdirecting resources that could be better used for more focused security measures.

Kraft always stands ready to work with the government to protect the safety of the food supply. Please do not hesitate to contact me at (847) 646-6125, if we can provide additional information that might be helpful.

Sincerely,

Jean E. Spence

Jean E. Spence
Senior Vice President
Worldwide Quality, Scientific Affairs and Compliance
cc: FDA Docket 02N-0276